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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,939	12/04/2006	Alexander Abbas	GNE-0267 R1-1	3703

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Arnold & Porter LLP (24126)
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EXAMINER	
LI, RUIXIANG	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
12/16/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,939	ABBAS ET AL.	
	Examiner	Art Unit	
	RUIXIANG LI	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

Applicant's amendment filed on 10/23/2009 has been entered. Claims 11-16 are pending and under consideration.

Withdrawn Objections and/or Rejections

The rejection of claims 11-14 and 16 under 35 U.S.C. 112, second paragraph, set forth in the previous office action mailed on 04/06/2009 is withdrawn in view of amended claims.

The objection to the title of the invention is withdrawn in view of amended title.

The objection to claims 11, 13, and 16 are withdrawn in view of amended claims.

Drawings

The specification refers to figures (beginning at page 89). It is noted that, however, Applicants have not submitted any drawings yet in the instant application. Applicants argue that drawings were submitted in the original PCT/US04/26249 as Appendix A. This is not persuasive because the drawings need to be submitted in the instant application even though they were submitted in the original PCT/US04/26249.

Claim Rejections Under 35 U.S.C.§101, 35 U.S.C. §112, 1st Paragraph

(i). 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

(ii). Claim 11 is rejected under 35 U.S.C. 101 because the claims invention is directed non-statutory subject matter.

Claim 11, as written, does not sufficiently distinguish over an antibody that exists naturally because the claim does not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "isolated" or "purified". See MPEP 2105.

(iii). The rejections of claims 11-16 under 35 U.S.C. § 101 and 35 U.S.C. §112, 1st paragraph are maintained. Claims 11-16 are rejected under 35 U.S.C. § 101 and 35 U.S.C. §112, 1st paragraph because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well-established utility.

Beginning at page 6 of Applicants' response, Applicants argue that the specification has provided specific utility for the claimed antibodies. Applicants argue that the

specification clearly indicates the specific conditions that can be diagnosed with the claimed antibodies, immune-related diseases or inflammatory related diseases. Applicants argue that the present application identified that PRO220 of the present invention are differentially expressed in isolated activated T cells as compared to isolated resting CD4+ T cells. Applicants argue that this biological activity is specific and reasonably correlated with immune-related disease. Applicants argue that Applicants have identified various types of immune-related diseases that may be diagnosed with the presently claimed methods.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. The specification discloses that the polypeptide of SEQ ID NO: 2120 show differential expression in isolated stimulated CD+ T helper cells as compared to unstimulated CD+ T help cells or isolated resting CD+ T helper cells (page 78, the 1st paragraph to 2nd paragraph) based upon the microarray analysis (Example 1). However, the specification fails to disclose whether the polypeptide of SEQ ID NO: 2120 increased in isolated stimulated CD+ T helper cells as compared to unstimulated CD+ T help cells or isolated resting CD+ T helper cells, and fails to disclose any specific immune related diseases or inflammatory immune responses in a mammal that can be diagnosed by the claimed method. The specification merely listed a long list of diseases. There is no evidence showing that the level of expression of a gene encoding the polypeptide of SEQ ID NO: 2120 correlates to any particular immune related diseases or inflammatory immune responses in a mammal.

Beginning at the bottom of page 8 of Applicants' response, Applicants argue that the specification has provided substantial utility for the claimed methods. Applicants argue that Applicants have shown that various PRO polypeptides of the present invention are differentially expressed in isolated CD4+ T cells activated by ICAM-1 and anti-CD28 as compared to isolated resting CD4+ cells. Applicants argue that these data demonstrate that PRO polypeptides of the present invention are useful as diagnostic markers for the presence of one ore more immune disorders. Applicants argue that CD4+ T cells are known to be important regulators of the inflammation. Applicants argue that knowing that PRO220 is over expressed in the activated T cell, a skilled artisan would recognize that PRO220 is associated with immune-related disease and can be used as a diagnostic marker for immune-related diseases.

Applicants' argument has been fully considered, but is not deemed to be persuasive because there is no evidence showing that the level of expression of a gene encoding the polypeptide of SEQ ID NO: 2120 correlates to any particular immune related diseases or inflammatory immune responses in a mammal. The specification does not even disclose whether the polypeptide of SEQ ID NO: 2120 increased in isolated stimulated CD+ T helper cells as compared to unstimulated CD+ T help cells or isolated resting CD+ T helper cells. The specification does not disclose that PRO220 is over expressed in the activated T cell.

Clearly, further research would be required to identify an immune disorder that can be diagnosed or treated. See *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966), noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."

Accordingly, the rejections of claims 11-16 under 35 U.S.C. § 101 and 35 U.S.C. §112, 1st paragraph are maintained.

Claim Rejections under 35 USC § 112, 2nd paragraph

(i). The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(ii). Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is indefinite because it recites "a therapeutically effective amount". Since the specification does not disclose treatment a particular disease and does not define the term, the claim is indefinite. Applicants have neither amended nor responded to this rejection.

Claim Rejections under 35 USC § 102 (b)

(i). The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(ii). Claims 11-16 are rejected under 35 U.S.C. 102 (b) as being anticipated by Hillman et al. (US 6,168,920 B1, Jan. 2, 2001). The basis for the rejection is set forth in the previous office action.

Applicants argue that claim 11 has been amended by adding a limitation, "wherein said antibody modulates activity of T cells". This is not persuasive because Hillman et al. teach a polypeptide that is 100% identical to the polypeptide of SEQ ID NO: 2120 of the present invention and an antibody that binds to the polypeptide of Hillman et al. is capable of performing the activity recited in claim 11.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/
Primary Examiner, Art Unit 1646

Ruixiang Li, Ph.D.
December 14, 2009